MICRO DIATHERMY SYSTEM

Type 1100

INSTRUCTION MANUAL

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Section 1

Introduction

The D.O.R.C. Micro Diathermy System is designed primarily for retinal detachment procedures (scleral diathermy and release of subretinal fluid). The instrument is also used for glaucoma procedures (cryclo diathermy and cauterization of lips of sclerotomy).

The destruction of skin and intraocular tumors, hemostasis, epilation and trichiasis.

The Micro Diathermy System is a mobile compact source of radio frequency (RF) power. The unit is used on line.

RF energy, at a frequency of 13.56 MHz is produced by a crystal controlled solid state oscillator. The energy intensity delivered to the electrode can be varied continuously from 0 watts to approximately 12 watts. The output is regulated so that RF current is constant at the preselected value.

The surgeon can control the intensity of burns more precisely, and with the shortest applications, perform scleral marking to localize retinal tears. In addition, the RF LEVEL control knob is marked in increments of ten from 0 to 10.
When the RF output section is activated a blue LED on the front panel will light and a buzzer will produce a constant tone.

Section 2

General Instructions.

2.1
Standard components of the Micro Diathermy System..

The standard components of the Micro Diathermy system are:

- Ophthalmic diathermy 13.56 MHz complete with power cord and foot switch.
- Diathermy with transillumination.
- Under water diathermy for both vitreous and anterior chamber surgery.
- Bipolar coagulation.
- Instruction manual

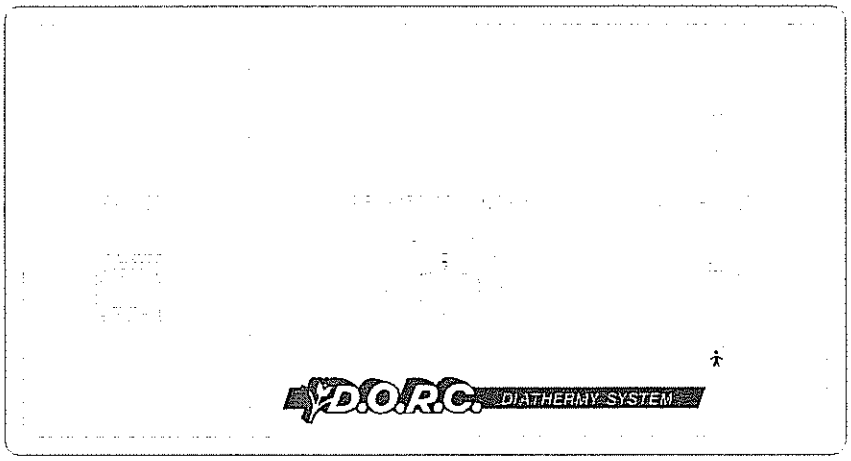

Fig. 1 Micro Diathermy system - Front View

2.2
Operating instructions.

A. Check if the electrical supply the unit needs is correct (at the back-side).

B. Plug the unit into the AC source outlet.

C.1. Assembling accessories :
The electrodes (1102-1111) are inserted into the handle assembly (1101) after unscrewing the chuck cap approximately one-half turn counterclockwise. After the electrode is oriented in the desired position, the cap is screwed down with very little finger pressure. Avoid over-tightening the cap as this may cause the threads to become stripped.

The electrode handle with cable (1101) is then plugged into the connector marked Instrument on the front panel. NEVER disconnect the cable by pulling on the cable itself.
The cable should be disconnected by grasping the connector between thumb and the fore-finger and pulling straight out.
If the cable is not disconnected in this manner, damage to the cable will result.

NEVER TRY TO SEPARATE THE CABLE FROM THE HANDLE AS BOTH CONSTITUTE AN INTEGRAL ASSEMBLY.

C.2. Coaxial Electrodes 1113

To replace a non-infusion type electrode 1113, carefully remove the threaded electrode assembly from its handle and replace with a new electrode using the same procedure as with the chorioretinal electrodes and the electrode handle with cable.

IMPORTANT : For sterilization instructions see section 3 .

2.3
Theory of operation

Diathermy is used in operations for retinal detachment to produce a burn of the pigment epithelium. This burn is obtained by the applications of localized RF current on the sclera.

A. Why High Frequency 13.56 MHz Power ?

The following consideration resulted in the selection of the 13.56 MHz :

1. Clinical tests have established that this frequency produces optimum burns of the pigment epithelium with the least possible damage to adjacent tissue such as the sclera and choroid.
2. High frequency produces very small localized burns whereas low frequency produces larger burns which are not as well localized.
3. With high frequency, the impedance of the sclera crust formation has less variation than with low frequency.
   It is thus possible to obtain more consistent burns repeatedly. The nominal scleral impedance is 600 ohms.
   The Micro Diathermy has been designed for a maximum output level variation of less than ± 10% at each RF LEVEL setting for scleral impedance which may vary over a range of 400 to 1000 ohms. This inherent design feature allows for an even greater consistency of burn.
4. Due to low impedance at high frequency, less voltage is required to produce a given burn than at low frequency.

B. How a burn is produced :

The precise physiological and electrical characteristics of RF scleral application are not yet fully known. Nevertheless, it is possible to distinguish three factors involved in producing a scleral RF burn.

1. The heat is produced by Joule's effect (the resistive part of the tissues in the current's path).
2. In high frequency applications, the heat is produced by dielectric losses in the capacitive part of the tissues.
3. Propagation of heat generated by the crust formation under the electrode's tip.

C. Factors affecting a Diathermy burn :

Several factors affect the nature of a burn obtained in scleral diathermy applications :

1. Voltage : The intensity of the burn is proportional to the voltage level for any given frequency.
If an insufficient reaction occurs in the scleral application, the voltage (RF level) must be increased.

A SCLERAL APPLICATION OVER ATTACHED RETINA SHOULD PRODUCE A SMALL GREY-WHITE SPOT IN THE RETINA.

2. Time : For a given burn intensity, the duration of application is inversely related to the voltage level. Low voltage must be applied for a longer time to obtain a burn equivalent to one obtained by applying high voltage for a shorter time.

3. Hydration : The moistness of the sclera affects the burn in two ways:
A. If the sclera is wet, the impedance is low. This decreases the voltage and reduces the burn.
B. A wet sclera causes wide dispersion of the current which also results in a less efficient burn.

4. Location : The thickness and impedance of the different layers of the eye are variable in different eyes and in different locations in the same eye.
The sclera is thicker and the impedance is lower in the posterior segment of the eye. The voltage level or the duration of application must be greater posteriorly than anteriorly.
The most consistent results are obtained when applications are made at equal distances from the limbus.

5. Pressure : Pressure does not seem to affect the diameter of a burn, although greater pressure will cause a more intense burn as it dries the sclera and decreases choroidal circulation.

Section 3

Cleaning and Sterilizing Instructions for Accessories

3.1

Reusable Accessories

The device is provided non-sterile. The device must be sterilized prior to first use. It requires decontamination and re-sterilization between patient procedures. The device may be sterilized using either EtO or Steam. Refer to the section entitled, "Sterilization (Prior to First Use)".

Warning!!!

Because sterilization effectiveness depends on the complete reprocessing of instrumentation (adequate cleaning, process control, maintenance of sterility from the point of processing to the surgical field), flash sterilization should not be used as the only or primary means of sterilization.

Sterilization (Prior to First Use)

Devices which are provided non-sterile require sterilization of all components prior to patient use. For general information relating to steam and ethylene oxide sterilization of surgical instruments, refer to the references outlined at the end of this section.
All devices to be sterilized should be wrapped using materials selected according to "AORN Recommended Practices for Selection and Use of Packaging Systems."

1. Wrap or pouch the reusable instrument components as recommended in "AORN Recommended Practices for Selection and Use of Packaging Systems."
2. Load the sterilizer in such a manner to allow exposure of all surfaces to the steriliant. Record the sterilization data in the appropriate records.
   Note: If the 1269 probe is being used, place the protective cap over the shaft before sterilizing.

Steam Sterilization Parameters

Gravity displacement steam sterilization

Wrapped items

Temperature	:	270°F to 275°F (132°C to 135°C)
Exposure time	:	15 to 30 minutes

Unwrapped items ("flash sterilization"):

Temperature	:	270°F (132°C)
Exposure time	:	10 minutes

Prevacuum steam sterilization

Wrapped items

Temperature	:	270°F to 275°F (132°C to 135°C)
Exposure time	:	3 to 4 minutes

Unwrapped items ("flash sterilization"):

Temperature	:	270°F (132°C)
Exposure time	:	4 minutes

Here are some recommended guidelines for steam sterilization:

- Never sterilize the accessories using dry air sterilization.
- Handle the accessories gently. They are precision instruments.
- During the sterilization process, do not allow any of the accessories to touch any other items.
- Use only demineralized water for sterilization.

Ethylene Oxide Sterilization Parameters

100% EtO cycles

Concentration of EtO	:	850 ±50 mg/l
Temperature	:	99°F to 117°F (37°C to 47°C)
Exposure time	:	3 to 4 hours
Relative humidity	:	70%

Following EtO sterilization, the illumination accessories must be aerated to remove any residual EtO gas. The aeration time must be sufficient to reduce the residues below the maximum levels as proposed in the "USA Federal Register", Volume 43, No. 122, June 23, 1978, pp. 27482-3.

Caution !!!

The effectiveness of sterilization methods other than that specified above is unknown and should be validated by the user.

Warning!!!

Remember that the suggested parameters are just guidelines. They represent industry standards, and should be capable of producing a sterile device. Because of variations in sterilization equipment and device bioburden, D.O.R.C. International is not able to provide more specific cycle parameters. ***It is the responsibility of each user to perform validation and verification of the sterilization equipment and cycle to ensure adequate sterility assurance level for these products.***

References:

- "ANSI/AAMI ST41 Good Hospital Practice, Ethylene Oxide Sterilization and Sterility Assurance."
- "AORN Recommended Practices for Steam and Ethylene Oxide Sterilization."
- "AAMI Good Hospital Practice: Steam Sterilization and Sterility Assurance", (1992B, 1993b, 1994b).
- EN550, "Sterilization of Medical Devices, Validation and routine control of Ethylene Oxide Sterilization."
- EN554, "Sterilization of Medical Devices, Validation and routine Control of Sterilization by Moist Heat."

Decontamination of Reusable Accessories
All reusable components must be thoroughly cleaned before resterilization. Sterilization should then be performed using the instructions provided above.

Caution !!!
The effectiveness of sterilization methods other than those specified above is unknown and should be validated by the user.

Caution !!!
The reliability of the sterilization process is affected by the number, type, and inherent resistance of organisms on the items to be sterilized. Soil and moisture inhibit sterilization and may produce toxic byproducts.

For additional general information regarding decontamination of surgical instruments, refer to "AORN Recommended Practices for Care of Instruments, Scopes, and Powered Surgical Instruments" (1997) and ANSI/AAMI ST35 (1996), "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and Nonclinical Settings."

Disassembly Instructions
Disassemble any device that has removable parts, and clean each part separately according to the following instructions:

Cleaning Instructions

1. Submerge and soak the devices in the enzymatic detergent solution for a minimum of two minutes.
   Note: Items which cannot be submerged or soaked, should be wiped with enzymatic cleaner prior to sterilization.
2. For devices with an internal lumen, flush enzymatic cleaner through the lumen using a cleaning syringe.
3. Rinse under distilled running water to remove surface suspended particles.
4. Flush the lumen with distilled water.
5. Perform a final rinse with distilled water.
6. Dry the outside of the devices and purge the lumens with compressed air. Drying may also be accomplished by rinsing or flushing with 70% alcohol.
7. Inspect the devices for cleanliness and damage. Call your local distributor for replacements.
8. Reassemble any devices which have been disassembled prior to sterilization.
   Note: The useful life of any surgical instrument depends on the conditions of use. Therefore, there is no absolute recommended number of reuses. Components should be discarded if there is any sign of wear or damage.

Re-sterilization Instructions
Re-sterilize the devices using the instructions provided in the section entitled "Sterilization (Prior to First Use)." See page 6.

Caution !!!
Devices labelled as "Single Use" are designed to be used one time only, and should not be reprocessed.

Section 4
Service Instructions

4.1
Replacing the Fuses

1. Turn off the power switch on the back of the unit. Unplug the power cord.
2. The fuses are located on the rear of the unit, inside the black box at the point where the power cord is attached. The fuse cover has two tabs. Squeeze these together, and pull the fuse assembly out.
3. Remove the old fuses. Replace them with two new fuses of the same type:

Voltage	Fuse	Dimensions
110/120VAC~	1 A slow-blow	5 x 20 mm
230/240VAC~	0,5 A slow-blow	5 x 20 mm

Table 1 - Fuse Replacement

The fuse type is also listed on the label on the rear of the unit.

4. Plug in the power cord and turn on the power switch on the rear of the unit.
5. ***Important!*** If the new fuses fail quickly, there may be something wrong with the unit. Call local distributor or D.O.R.C. International b.v. for instructions.

4.2
Recommended Spare Parts

D.O.R.C. International b.v. recommends that you keep the following parts on hand. If a problem develops, this will allow you to return the unit to service quickly.

Part	Description
Fuse - 110/120VAC~	1 A slow-blow
Fuse - 230/240VAC~	0,5 A slow-blow

Table 2 - Recommended Spares

4.3
Periodical Instructions for Preventive Inspection and Maintenance

For optimum performance, the D.O.R.C. Micro Diathermy System requires periodic inspection of the accessories and the circuit breaker.

Service manual on request available through local distributor or D.O.R.C. International b.v.

4.4
Returning the Unit for Service

1. Before returning the unit to D.O.R.C. International b.v. for service, please contact the Service Department:

   Service Department
   D.O.R.C. International b.v.
   Scheijdelveweg 2
   3214 ZG Zuidland
   The Netherlands

   Tel: 31-181-458080
   Fax: 31-181-458090

2. Please try to protect the unit as much as possible during shipping. It is best to use the original packaging if it is available.

Section 5

Optional Accessories

1101	Electrode handle with cable. (the on/off switch on the handle will only work in combination with a Mira diathermy unit), with the D.O.R.C. unit this handle can be operated by means of the foot switch.
1102	Electrode, buff, 2 mm. fine tip; for perforation and release of subretinal fluid.
1103	Electrode, black, for surface or partially penetrating diathermy.
1104	Electrode, green, for surface diathermy.
1105	Electrode, grey, for localization posterior to the equator.
1106	Electrode, brown, for localization at or anterior to the equator.
1107	Electrode, aqua, 3 mm. fine tip; for tumor destruction.
1108	Electrode, pink, 4 mm. fine tip; for tumor destruction.
1109	Electrode, brown, 5 mm. fine tip; for tumor destruction.
1110	Electrode, buff, two stripes, 1.0 mm. fine tip; for penetrating diathermy.
1111	Electrode, buff, three stripes, 1.5 mm. fine tip; for penetrating diathermy.
1112	Electrode handle with fiber optics bundle, coaxial cable and scleral transillumination electrode.
1113	Electrode handle with cable complete with straight coaxial electrode without infusion 20 gauge (0,9 mm.).
1115	Bipolar coagulation forceps 12 cm angled blunt tips 0.5 mm. with cable.
1115A	Diathermy cable for 1115 and 1116 forceps.
1116	Bipolar coagulation forceps, straight 12 cm. blunt tips, 0.5 mm. with cable.
1117	Sterilizable electrode holder.
1120	Reusable intra-ocular (coaxial diathermy electrode 0.9 mm. (20 gauge) with handle for controlling retinal bleeders.
1120A	Diathermy cable for probes 1120,1121 and 1122.
1121	Reusable coaxial probe 1.3 mm. with handle for precise hemostasis by a gentle wiping motion.

1122	As 1121, but with 45° curved tip.
1124	Endodiathermy probe with tapered tip.
1281-D	Flute needle with the capability of retrograd flushing and endo diathermy. New instrument for aspiration of blood as well as coagulation of the bleeding spot and flushing back unwanted tissue.

Section 6
SPECIFICATIONS

GENERAL:

Apparatus	:	MICRO DIATHERMY SYSTEM
Type	:	Type 1100
Weight	:	5,5 Kg
Dimensions	:	13 x 22,5 x 29 cm.

MAINS INPUT:

Mains supply	:	100-110 VAC (50/60 Hz) 230-240 VAC (50/60 Hz)
Fuses	:	2x at 100/110VAC 1 AT 2x at 230/240VAC 500 mAT
Power Consumption	:	45 VA

OUTPUT (values at room temperature)

RF output power	:	0-10 Watt max., see figure 2
RF Frequency	:	13.56 Mhz, Cristal controlled.

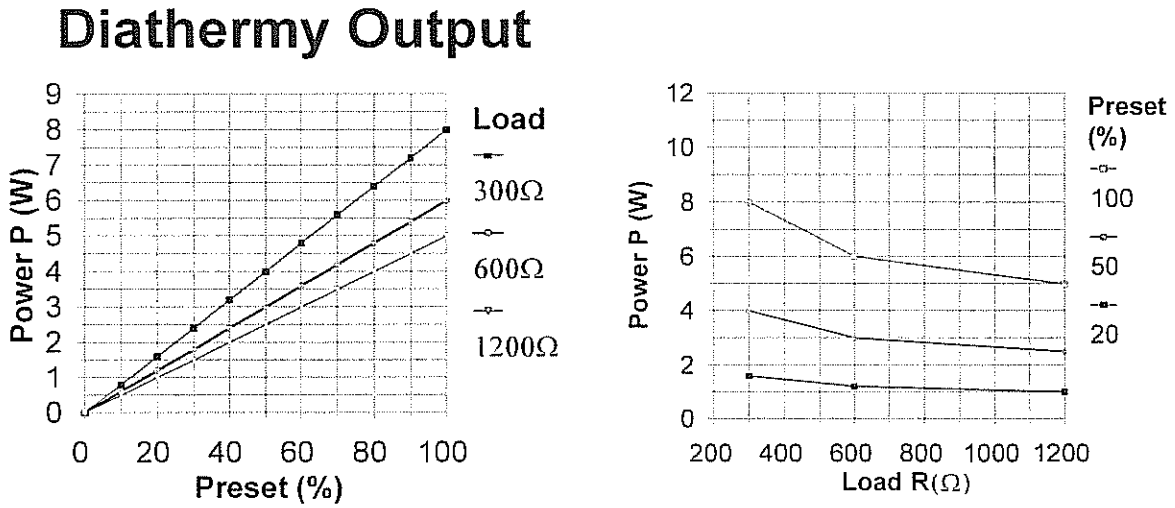

Figure 2 - Diathermy output

AMBIENT CONDITIONS:

Operating temperature : 15-40°C
Humidity : 85% Max.

The D.O.R.C. Diathermy system complies with the safety standards as described in the international norm IEC601-1, Type BF, Class I

Section 7

Warnings

A warning indicates a potentially harmful situation to yourself or others.

Electric shock hazard
This unit contains high voltage circuits.

After performing any repair, calibration procedure performs a final electrical safety check and leakage current test.

Unplug the power cord before cleaning or servicing the unit. Should the power cord or plug become cracked, frayed, broken or otherwise damaged, it should be replaced immediately.

Do not touch any exposed wiring or conductive surface, while the cover is off and the unit is energized. The voltages present, when electric power is connected to this unit, can cause injury or death.

Never wear a grounding wrist strap when working on an energized unit. The operator should now perform any servicing except as specifically stated in the Instruction Manual.

Do not, under any circumstances, perform any testing or maintenance on medical instruments, while they are being used to monitor a patient.

Always turn this unit off before cleaning.

Explosion hazard
Never use this unit in the presence of flammable anesthetics.

EMC between this unit and other devices. It is important to install and use the equipment in accordance with the instructions in order to prevent interference with other devices in the vicinity.

Cautions
A caution indicates a condition that may lead to equipment damage or malfunction.

Electrostatic discharge through the printed circuit boards will damage the components of this unit. Handle all circuit boards (replacements and defective) by their non-conductive edges and use anti-static containers, when transporting them. Before servicing the equipment, ground yourself and the tool to discharge any accumulated static charge, by wearing a static tool wrist strap. Use hospital-grade grounded receptacle only.

Servicing of this product, in accordance with the Service Manual, should never be undertaken in the absence of proper tools, test equipment and the most recent revision of the Service Manual, which must be clearly and thoroughly understood.

Do **NOT** apply tension on the power cord. Check rear panel voltage setting before connecting this unit to AC main power.
NEVER IMMERSE THIS UNIT IN LIQUID !!!

Section 8

Warranty

D.O.R.C. International b.v. warrants that all possible care was used in the choice of materials and manufacture of its products.

D.O.R.C. International b.v. shall not be liable for any incidental or consequential loss, damage or expense, arising from abuse of its products. However, if D.O.R.C. International b.v.'s investigation shows that its products were defective at the time of shipment by D.O.R.C. International b.v., products will be replaced/repaired at no charge.

Otherwise all D.O.R.C. International b.v. equipment is covered with a full year warranty, which does not cover the accessories.

D.O.R.C. International b.v. neither assumes or authorizes any other person to assume for it, any other or additional liability or responsibility in connection with its products.